

Food and Drug Administration, HHS

§ 862.3850

any of the addictive narcotic pain-relieving opiate drugs in blood, serum, urine, gastric contents, and saliva. An opiate is any natural or synthetic drug that has morphine-like pharmacological actions. The opiates include drugs such as morphine, morphine glucuronide, heroin, codeine, nalorphine, and meperidine. Measurements obtained by this device are used in the diagnosis and treatment of opiate use or overdose and in monitoring the levels of opiate administration to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3660 Phenobarbital test system.

(a) *Identification*. A phenobarbital test system is a device intended to measure phenobarbital, an antiepileptic and sedative-hypnotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3670 Phenothiazine test system.

(a) *Identification*. A phenothiazine test system is a device intended to measure any of the drugs of the phenothiazine class in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of phenothiazine use or overdose.

(b) *Classification*. Class II.

§ 862.3680 Primidone test system.

(a) *Identification*. A primidone test system is a device intended to measure primidone, an antiepileptic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of primidone overdose and in monitoring levels of primidone to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3700 Propoxyphene test system.

(a) *Identification*. A propoxyphene test system is a device intended to measure propoxyphene, a pain-relieving drug, in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treat-

ment of propoxyphene use or overdose or in monitoring levels of propoxyphene to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3750 Quinine test system.

(a) *Identification*. A quinine test system is a device intended to measure quinine, a fever-reducing and pain-relieving drug intended in the treatment of malaria, in serum and urine. Measurements obtained by this device are used in the diagnosis and treatment of quinine overdose and malaria.

(b) *Classification*. Class I.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21450, June 8, 1988; 65 FR 2310, Jan. 14, 2000]

§ 862.3830 Salicylate test system.

(a) *Identification*. A salicylate test system is a device intended to measure salicylates, a class of analgesic, antipyretic and anti-inflammatory drugs that includes aspirin, in human specimens. Measurements obtained by this device are used in diagnosis and treatment of salicylate overdose and in monitoring salicylate levels to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3840 Sirolimus test system.

(a) *Identification*. A sirolimus test system is a device intended to quantitatively determine sirolimus concentrations in whole blood. Measurements are used as an aid in management of transplant patients receiving therapy with sirolimus.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Sirolimus Test Systems." See § 862.1(d) for the availability of this guidance document.

[69 FR 58259, Sept. 30, 2004]

§ 862.3850 Sulfonamide test system.

(a) *Identification*. A sulfonamide test system is a device intended to measure sulfonamides, any of the antibacterial drugs derived from sulfanilamide, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of sulfonamide

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overdose and in monitoring sulfonamide levels to ensure appropriate therapy.

(b) *Classification*. Class I.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21450, June 8, 1988; 65 FR 2310, Jan. 14, 2000]

§ 862.3870 Cannabinoid test system.

(a) *Identification*. A cannabinoid test system is a device intended to measure any of the cannabinoids, hallucinogenic compounds endogenous to marijuana, in serum, plasma, saliva, and urine. Cannabinoid compounds include *delta*-9-tetrahydrocannabinol, cannabidiol, cannabinol, and cannabichromene. Measurements obtained by this device are used in the diagnosis and treatment of cannabinoid use or abuse and in monitoring levels of cannabinoids during clinical investigational use.

(b) *Classification*. Class II.

§ 862.3880 Theophylline test system.

(a) *Identification*. A theophylline test system is a device intended to measure theophylline (a drug used for stimulation of the muscles in the cardiovascular, respiratory, and central nervous systems) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3900 Tobramycin test system.

(a) *Identification*. A tobramycin test system is a device intended to measure tobramycin, an aminoglycoside antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3910 Tricyclic antidepressant drugs test system.

(a) *Identification*. A tricyclic antidepressant drugs test system is a device intended to measure any of the tricyclic antidepressant drugs in serum. The tricyclic antidepressant drugs include imipramine,

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desipramine, amitriptyline, nortriptyline, protriptyline, and doxepin. Measurements obtained by this device are used in the diagnosis and treatment of chronic depression to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3950 Vancomycin test system.

(a) *Identification*. A vancomycin test system is a device intended to measure vancomycin, an antibiotic drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

(b) *Classification*. Class II.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

Subpart A—General Provisions

Sec.

864.1 Scope.

864.3 Effective dates of requirement for pre-market approval.

864.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Biological Stains

864.1850 Dye and chemical solution stains.

864.1860 Immunohistochemistry reagents and kits.

Subpart C—Cell and Tissue Culture Products

864.2220 Synthetic cell and tissue culture media and components.

864.2240 Cell and tissue culture supplies and equipment.

864.2260 Chromosome culture kit.

864.2280 Cultured animal and human cells.

864.2360 Mycoplasma detection media and components.

864.2800 Animal and human sera.

864.2875 Balanced salt solutions or formulations.

Subpart D—Pathology Instrumentation and Accessories

864.3010 Tissue processing equipment.

864.3250 Specimen transport and storage container.

864.3260 OTC test sample collection systems for drugs of abuse testing.

864.3300 Cytocentrifuge.

864.3400 Device for sealing microsections.

864.3600 Microscopes and accessories.